January 8, 1999

This document was submitted to EPA by a registrant in connection with EPA's evaluation of this chemical, and it is presented here exactly as submitted.

February 16, 1998

Mr. Tom Moriarty
Chemical Review Manager - Oxydemeton-methyl
OPP/SRRD (7508W)
Environmental Protection Agency
401 M. St. SW
Washington, D.C. 20460

Re: Gowan Comments on EFED's Memo Dated September 11, 1997 and the draft Reregistration Eligibility Decision Chapter for Oxydemeton-methyl (ODM)

Dear Mr Moriarty:

Gowan Company submits the following comments on the referenced EFED memo and accompanying draft RED chapter, which were sent to us by the Agency on November 5, 1997.

EFED has recommended or required a number of additional studies, including a battery of environmental fate studies with certain metabolites. Also, concern has been expressed regarding the presumed chronic risk of parent ODM and certain metabolites to birds and mammals, and the acute toxicity of ODM to bees. We are concerned that a number of conclusions have been based on toxicity data which have been erroneously interpreted and on inaccurate exposure assumptions. As will be discussed in detail, below, we believe that ample data are available which will permit EFED to reverse several conclusions or recommendations.

Since EFED determined that acute risk to birds and mammals is expected to be minimal and that acute and chronic risk to freshwater fish and invertebrates is expected to be low, these issues are not discussed in this submission.

I. REQUESTED ENVIRONMENTAL FATE STUDIES

Concern has been expressed that two metabolites, 2-(ethylsulfinyl) ethane sulfonic acid and 2-(ethylsulfonyl) ethane sulfonic acid may be persistent and that environmental fate data are needed for these. EFED has requested a total of 5 studies, including aerobic aquatic metabolism and soil adsorption/desorption for each metabolite, plus an additional field dissipation study that monitors for both metabolites. We estimate the cost of these studies to be about $500K - $750K. The stated purpose for requesting these studies is to provide inputs for ecological risk assessement and EFED has indicated that the value of this information is high. To the contrary, since <u>there are no toxicological issues</u> associated with the metabolites, the requested data are not needed for the purpose of conducting a risk assessment.

We are puzzled by EFED's concern over these two metabolites, since they also have concluded that "these two metabolites are not believed to have any mammalian toxicity and probably are not a human health concern in drinking water". We believe it also should be noted that the metabolites have been found in plant (wheat) and animal (poultry) metabolism studies, have been reviewed by the Agency's Health Effect Division (HED) and are not considered to be metabolites of toxicological concern. Further, the HAZID Assessment Committee of HED

recently defined cholinesterase inhibition as the appropriate toxicological endpoint for 1) acute and chronic dietary, 2) short, intermediate and chronic occupational and 3) inhalational risk assessment for ODM. The sulfonic acid metabolites are not cholinesterase inhibitors.

Thus, there is no reasonable expectation whatsoever that the metabolites pose any toxicological risk to wildlife. We point out that in the draft RED chapter, ecological risk assessment is defined as the integration of exposure and toxicity data, which can be expressed numerically as a risk quotient (RQ) with the formula:

RQ = Exposure/Toxicity

Therefore, according to EFED's own definition of risk assessment, and the lack of any toxicological issue associated with the metabolites, we conclude that the ecological risk posed by the sulfonic acid metabolites is zero.

In any event, data are available which show clearly that the two metabolites are not persistent. Bayer Corporation, the previous ODM registrant conducted an abbreviated soil dissipation study in conjunction with the State of California's AB 2021 data requirements. We can find no record that this study was submitted to the Agency; and it is provided at this time.

In this study, soil was collected from untreated areas at the Fresno and Chular tests sites described in MRID 41422101. The soils were transported to the testing facility in Madera, California and following sieving, the soils were filled to a depth of about 5" in a series of one-gallon test vessels. The vessels were treated with an application of radiolabeled ODM at a rate of 1# ai/A to the surface of the soil; and analyses were conducted at intervals up to 60 days.
Both 2-(ethylsulfinyl) ethane sulfonic acid and 2-(ethylsulfonyl) ethane sulfonic acid were formed in both soils. Half-lives were calculated assuming first-order reaction kinetics, which overestimates degradation time, since first-order kinetics assume that no additional material is added into the system which would be the case as parent material degrades. In addition, it may reasonably be suggested that degradation of sieved soil contained in a vessel would occur more slowly than in a microbially undisturbed, open field. The half-life for 2-(ethylsulfinyl) ethane sulfonic acid was 5.3 days and 6.4 days at the Fresno and Chular sites, respectively. The half-life for 2-(ethylsulfonyl) ethane sulfonic acid was 4.5 days and 8.5 days for these sites.

In view of the lack of persistence of the sulfonic acid metabolites, and the absence of any toxicological issue associated with these, we believe that additional environmental fate work with these metabolites is unwarranted.

II. CHRONIC RISK TO BIRDS AND MAMMALS

The presumption of chronic risk to birds and mammals is based on certain toxicity data which we believe have been erroneously interpreted and on exposure assumptions derived from a modified Hoerger and Kenaga model, which grossly overestimates residues that would be present in non-crop food items in or near treated fields or orchards.

Chronic avian risk

The toxicological endpoint upon which the avian chronic risk quotients have been based is a presumed NOEC of 1.8 ppm in a Northern bobwhite quail 1-generation reproduction study. The Agency has stated that statistically significant differences were noted at the 6.9 ppm treatment level for the 14 day old survivor weights. In addition, the number of eggs laid per hen and the number of eggs set per hen were considered to be statistically different from the control at both the 6.9 and the 17.3 ppm treatment group. It may be noted that the above parameters at the 6.9 ppm treatment level were not found to be statistically different by the study authors.

In any case, the original Data Evaluation Record for this study was recently made available to us. Page 8 of the DER summarizes the statistical analyses. Based on this, it is evident that the apparent slight decrease in 14 day old survivor weight at the 6.9 ppm (10 ppm nominal) treatment level is irrelevant, since no statistical difference in this parameter was observed at the 17.9 (30 ppm nominal) treatment level. Regarding the difference in the number of eggs laid and set per hen, the Agency's analysis simply suggests a slight increase in these parameters at the 6.9 ppm treatment level. We believe that apparent slight improvements in these reproductive parameters are not indicative of adverse effects, and therefore are inappropriate to use in any risk assessment. The pertinent chronic avian NOEC is 6.9 ppm.

Estimated environmental concentrations

EEC's were derived by EFED for four use patterns: 1) **cabbage and cotton** - 3 applications of 0.75# ai/A with a 7 day retreatment interval, 2) **corn and sorghum** - 2 applications of 0.50# ai/A with a 7 day retreatment interval, 3) **alfalfa** - 2 applications of 0.75# ai/A with a 14 day retreatment interval and 4) **citrus** - 2 applications of 1.88 # ai/A with a 14 day retreatment interval.

Maximum EEC's of 1 - 473 ppm and average EEC's of 1 - 76 ppm have been estimated for these use patterns using the Hoerger-Kenaga model.

However, it is not necessary to employ theoretical models to estimate potential residues, since a wealth of actual data is available. Much more realistic EEC values can be estimated from crop magnitude of the residue trials. Measured residues on the day of final treatment (0-day) are available for several of the crops and use patterns modeled by EFED. It should be noted that even using actual measured residues significantly overestimates exposure for a number of reasons.

First, the maximum number of applications permitted on the label is not reflective of typical usage. As stated in previous correspondence, Gowan's and EPA's (Biological and Economic Analysis Division) estimates of actual use match quite closely. Both the Agency and Gowan have agreed that the typical use for ODM is usually one, occasionally two and rarely three applications per season. Therefore, little risk of repeated exposures is actually posed to wildlife.

Secondly, it must be remembered that in standard commercial crop production, non-crop grasses and broadleaf plants are considered to be weeds and every effort is made to eliminate these in

and around cultivated fields. Thus, the likelihood that these potential food items would actually be present is extremely low.

In addition, it should be noted that intentionally directed treatment to a crop overestimates residues that would be expected to be present on off-target vegetation or other food items. Related to this, we call EFED's attention to the stringent spray drift management language currently mandated on the ODM end-use label.

Finally, we point out that the typical diets of birds and mammals have not been considered. For example, it is not reasonable to suppose that an animal consumes any food item, exclusively. In addition, many animals do not consume some food items at all.

Residue data for corn forage, alfalfa, and cole crops are presented, below.

CORN FORAGE

Data are available from fifteen trials in corn forage (MRID's 00044956, 00090456, 00107030 and 00152371) in which residues were analyzed on the final day of application (0-day). In these trials, 2-3 applications of 0.5# ai/A were made, with retreatment intervals of 6 to 9 days. Residues on corn forage ranged from 4.84 ppm to 23.5 ppm. The average residue was 10.27 ppm. We point out that average residues are the appropriate values to consider for chronic risk assessment.

Measured residues at 0 days following application of ODM to corn forage

Site	Trial #	Rate # ai/A	# Apps	Retreat. Interval	ppm at 0 days
WI	53291	0.50	3	7, 7	6.60
TX	53445	0.50	3	7, 7	5.57
TX	53447	0.50	2	7	6.56
MN	54335	0.50	3	7, 7	9.20
TX	53526	0.50	3	7, 9	23.5
FL	54352	0.50	3	7, 7	9.25
FL	54342	0.50	3	6, 7	6.98
MO	54341	0.50	3	7, 7	4.84
TX	67457	0.50	3	8, 7	16.8
TX	67459	0.50	3	8, 7	11.8
CO	67491	0.50	3	7, 7	7.21
CO	67492	0.50	3	7, 7	6.60
CO	67493	0.50	3	7, 7	16.7
CO	67494	0.50	3	7, 9	13.6
CO	67494	0.50	3	7, 9	8.82
					Ave. = 10.27

ALFALFA

Data are available from thirteen trials in alfalfa in which residues were analyzed on the day of application (MRID#'s 00090456, 00120209 and 00152371). The data strongly corroborate residues found in corn forage. In these trials, 1-7 applications of 0.25 - 0.5# ai/A were made, with retreatment intervals of 14 - 50 days. Residues on alfalfa ranged from 3.82 ppm to 26.2 ppm. The average residue was 10.93 ppm. For those trials in which a 0.5x rate was used (0.25# ai/A), residues have been extrapolated to reflect the maximum 0.5# application rate in alfalfa. Extrapolated residues are indicated in parentheses in the ppm at 0 days column of the table, below.

Measured residues at 0 days following application of ODM to alfalfa

Site	Trial #	Rate # ai/A	# Apps	Retreat. Interval	ppm at 0 days
AZ	66293	0.50	7	14, 42, 49, 25, 24, 50	9.73
AZ	66292	0.25	7	14, 42, 49, 25, 24, 50	6.00 (12.00)
AZ	66294	0.25	7	14, 42, 49, 25, 24, 50	2.24 (4.48)
AZ	66295	0.50	7	14, 42, 49, 25, 24, 50	3.82
NV	51380	0.25	1		5.72 (11.4)
NV	51383	0.50	1		9.44
AZ	51196	0.25	1		13.1 (26.2)
OR	51193	0.50	1		12.8
CA	51199	0.50	1		12.2
OR	51200	0.50	1		6.72
OR	51201	0.25	1		4.28 (8.56)
OR	51202	0.25	1		6.24 (12.48)
CA	51203	0.25	1		6.16 (12.32)
					Ave. = 10.93

COLE CROPS

Data are available from 18 trials (MRID#'s 00070840, 00095522, 00120207, 00124231 and 00152371) in broccoli, cauliflower and brussels sprouts in which residues were analyzed on the day of application. The use patterns examined were 1-3 x 0.33 - 1.0 ai/A, with 7 - 17 day retreatment intervals. Residues in cole crops ranged from 0.26 - 6.73 ppm, with an average residue of 2.20 ppm. Residues extrapolated to the cabbage rate of 0.75# ai/A are indicated in

parentheses in the ppm at 0 days column of the table, below.

Measured residues at 0 days following application of ODM to cole crops

Site	Trial #	Rate # ai/A	# Apps	Retreat. Interval	ppm at 0 days
Broccoli					
NY	9620	0.75	1		3.4
CA	68840	0.50	3	7, 7	6.62 (9.93)
CA	68839	0.50	2	7	3.20 (4.8)
CA	68838	0.50	1		4.06 (6.09)
Cauli-flower					
CA	24610	0.75	3	7, 7	1.04
Brussels sprouts					
CA	82487	0.50	3	12, 17	2.75 (4.13)
TX	82488	0.50	3	7, 8	1.34 (1.95)
FL	82489	0.50	3	7, 7	0.87 (1.31)
CA	82490	0.75	3	12, 7	4.89
TX	82491	0.75	3	7, 8	0.52
FL	82492	0.75	3	7, 7	0.39
CA	69177	0.50	3	7, 7	1.92 (2.88)
CA	69178	0.75	3	7, 7	3.05
CA	68696	0.75	3	7, 7	10.1
CA	68695	0.50	3	7, 7	0.24 (0.36)
CA	24442	0.75	3	14, 7	1.16
CA	24286	0.33	1		0.81 (2.44)
CA	24286	1.0	1		3.59 (2.69)
					Ave. = 3.40

In summary, actual measured residues from crop field trials in corn forage, alfalfa and cole crops show clearly that the Hoerger/Kenaga model vastly overestimates residues that could be present in avian or mammalian food items following the use of ODM. For corn forage an average

residue of 10.27 ppm was found following 2-3 applications of 0.5# ai/A For alfalfa, average residues of 10.93 ppm were found following 1-7 applications of 0.25 - 0.5# ai/A. For cole crops, an average residue of 3.40 ppm was found following 1-3 applications of 0.33 - 1.0 ai/A.

Residue decline data

EFED has indicated its willingness to consider residue decline data to refute or confirm the supposition that ODM and the sulfonic acid metabolites pose chronic risk to birds or mammals. In view of the fact that HED does not consider the sulfonic acid metabolites to be toxicologically

significant for acute, intermediate or chronic dietary exposure and does not require these materials to be monitored in crop field trials or included in the tolerance expression for ODM, we request clarification from EFED concerning the utility of metabolite foliar decline information for use in bird or mammalian dietary risk assessment.

Foliar decline data in cauliflower, cotton, bell pepper and sugar beet foliage are available for ODM (and its relevant metabolite, ODM sulfone) from study MRID 43821401. These data are presented as Attachment 1. Residue decline in foliage is rapid. For all crops, residues dropped by about 50% to 85% of levels observed at day zero after two days (cauliflower - 85%, cotton - 49 %, bell pepper - 52 %, sugar beet - 64%. The average decline for the four crops examined after 2 days was 62.5%. The average decline after 7 days was 83.9%.

Chronic risk to birds and mammals

As shown above, ODM degrades quickly, thus any exposure of wildlife would be limited to sporadic and brief, rather than chronic intervals. It may be noted that the avian chronic endpoint has been based on a 21-week feeding study and the mammalian chronic endpoint has been based on a two-generation reproduction study, in which test animals are dosed continuously for approximately six months. There is simply no use scenario imaginable that would result in continuous dietary exposure of wildlife to ODM at NOEC levels for these long-term intervals.

Nevertheless, even if an Armageddon-caliber worst case scenario were envisioned for chronic risk, the residue decline data show that RQ's would not be exceeded for any use pattern after one week. One week does not represent chronic exposure. The assumptions in this worst case scenario are 1) residues on the worst case food item (short grass) are considered equivalent to those found on alfalfa (which had the highest average residues) after direct treatment at the maximum label rate 2) toxicology endpoints from either 21 week or 6 month forced exposure regimes are utilized for short term exposure risk assessment and 3) wildlife in or near treatment areas are assumed to eat a diet completely restricted to short grass, the worst case food item.

If it is assumed that the highest average residue of 10.93 ppm from alfalfa trials is present on short grass, and if these residues are extrapolated to the highest label rate of 1.88# ai/A in citrus, the 0 day EEC for short grass in citrus would be 41.09 ppm (10.93 x 1.88/.50). Using the average residue decline of 83.9% at one week shown above, the 7 day EEC would be 6.62 ppm. Chronic LOC's are not exceeded after one week, even assuming the completely unrealistic scenario used, above. The RQ for birds would be 0.96 and the RQ for mammals would be 0.75.

We conclude that ODM poses no chronic risk to birds or mammals.

III. ACUTE TOXICITY TO BEES

It was noted in the draft RED chapter that EFED does not currently assess risk to nontarget insects. In view of this, we believe it is inappropriate for EFED to suggest additional label language to mitigate risk that it has not evaluated. We point out that the toxicity of ODM to bees was evaluated by EEB in conjunction with the ODM Reregistration Standard. EEB concluded that although technical ODM was moderately to highly toxic to adult honeybees exposed to

direct application, the toxicity of foliar residues of the end-use product to bees was low. We conclude that the existing bee-caution label language remains appropriate for the ODM end-use label; and that a label amendment specifying that applications should be made at night when feasible is not necessary

IV. SUMMARY

1. Information is presented which shows that the sulfonic acid metabolites are not persistent. In view of this, and the fact that there is no toxicological issue associated with these materials, additional environmental fate studies are unwarranted.

2. Measured residues from crop field trials demonstrate clearly that the EEC's derived with the Hoerger-Kenaga model greatly overestimate residues that would be present on avian or mammalian food items. Foliar residue decline data for ODM show rapid residue reduction.

3. The low levels of ODM that could be expected to be present on nontarget food items and the rapidity with which ODM degrades obviates any possibility of chronic risk to birds or mammals.

4. The label modifications suggested in association with presumed risk to bees and other non-target insects are unnecessary, since it has been shown that the toxicity of foliar residues of the product actually used in the field is low.

5. The recommendations to reduce the number of applications to 1 per year and to reduce maximum label rates are unfounded, since neither ODM nor the non-persistent sulfonic acid metabolites pose chronic risk.

6. EFED concluded that acute risk to birds and mammals is expected to be minimal and that acute and chronic risk to freshwater fish and invertebrates is expected to be low. We have presented extensive information in this submission which shows that ODM does not pose chronic risk to birds or mammals. Accordingly, we request that EFED reconsider their recommendation that the 9 uses currently removed from the marketing label may not be reinstated, in order to reduce risk to nontarget species.

We respectfully request a written reply from the Agency concerning these issues.

Sincerely,

Elizabeth Codrea
Regulatory Product Manager

Attachment 1: Foliar residue decline of ODM/ODMS in 4 crops
Enclosure: Abbreviated Soil Dissipation of ^{14}C-Oxydemeton-methyl on California Soils

ATTACHMENT 1

FOLIAR RESIDUE DECLINE OF ODM/ODMS IN 4 CROPS